IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. USP LABS, LLC, et al., Defendants.	)	**Case No. 3:15-CR-00496-L** Dallas, Texas May 10, 2018 10:00 a.m. MOTION HEARING (Continued from 05/09/2018)

TRANSCRIPT OF PROCEEDINGS
BEFORE THE HONORABLE RENEE HARRIS TOLIVER,
UNITED STATES MAGISTRATE JUDGE.

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THE CLERK: All rise.

THE COURT: Good morning.

ALL COUNSEL: Good morning, Your Honor.

THE COURT: Please be seated. We're back on the record in Case No. 3:15-CR-496-L. And gentlemen, yesterday when we left off, I guess our plan today was to hear arguments on the motions to dismiss and to find out from you what you want to do going forward on the remaining motions to exclude experts. So maybe we should take up the last thing first, then.

A VOICE: (faintly) Your Honor, we have made -- by agreement with the Government, and we have notified the Court and I believe that all of the Defendants have no objection to submitting the issue of (inaudible) and our objection to the Government's on the papers, calling no witnesses.

THE COURT: Okay. Okay. And so on the papers already submitted? I'm not --

A VOICE: Already submitted. Yes, Your Honor.

THE COURT: Okay. Good. Thank you. Yes, sir?

MR. RUNKLE: Yes. And to the extent I think you didn't cover our experts, but we -- we also agree. We're not going to put our experts on. We're not going to insist on a full *Daubert* hearing.

THE COURT: Okay.

MR. RUNKLE: And I'd just like to make clear on the record, I think that this is a waiver of the argument that -- the fact that no ***Daubert*** hearing was conducted is not a grounds for appeal. Is that --

A VOICE: No, we --

MR. RUNKLE: That's --

A VOICE: We're in agreement that that hearing is no longer going to be held.

THE COURT: Okay.

MR. RUNKLE: Okay. Thank you.

THE COURT: And as to the motions to dismiss, my thought is that it would be better and easier for me if we basically took it by counts, starting with the motion to dismiss Counts 2 through 4 on the basis of the statute of limitations and going on from there. So are you all prepared to argue on that one first? Okay.

Okay. And again, I think Jane mentioned it before I came in. We have the invisible court reporter today, and so you'll have to speak into the microphones. It doesn't matter if they're amplifying well, but that's what the recorder hears. So you have to be in the microphones there.

MR. WEINGARTEN: Okay.

THE COURT: Thank you.

MR. WEINGARTEN: Good morning, Your Honor. My name is

Reid Weingarten and I'm a lawyer at Steptoe & Johnson in Washington and I'm here representing USPLabs.

You know, we discussed how best to proceed this morning. And based upon my observation to the Court yesterday and what my friends and brothers of the bar told me about how the Court operates, I know you've read all the cases, I know you've read the papers, I know you're prepared to go.

I also think, in the main, all of these motions have been well briefed. I commend the Government. They're smart lawyers. They write well.

So what we believe today for purposes of these arguments is simply to supplement. If there are new things that we've thought of or things that we can't help but saying, we're going to offer those. But, you know, generally rely on the briefs and obviously be available to answer any and all questions.

Okay. For purposes of the statute of limitations argument, I think it's fairly straightforward. I think everybody is in agreement that, absent application of 3292, the DMAA counts go. They're time-barred.

And obviously the backdrop to this is it seems clear that the Government was right up to the edge of the statute on DMAA. And as I'm sure the Court is familiar, this product, the DMAA product, the Jack3 product, accounts for the enormous amount of sales and profits for USPLabs. And because of some play with the FDA, that product was withdrawn from the market. It's a

long, complicated story. But the centerpiece for the life and blood of USPLabs is DMAA, so the way we interpret the timeline here was the Government wanted to squeeze DMAA into the indictment, they were running up to the statute of limitations, and they turned to 3292.

Now, 3292 has been in the law for a long time, since 1984. I'm familiar with it. Prosecutors use it frequently. And obviously, the centerpiece for this issue is whether or not there was an official request. Whether or not, by a preponderance of the evidence, they made this presentation to Judge Fitzwater. And the long and short of it is there is a treaty that covers this between China and the United States. It's an exhibit. And the treaty provides obligations on the Government. They must present certain information to the Chinese for it to be successful. By treaty. Simply stated, the Government, for whatever reason, did not show what it presented to the Chinese authorities to Judge Fitzwater. They simply said they did.

THE COURT: Is that a requirement, though?

MR. WEINGARTEN: I believe so. And I -- I believe so. I mean, it's sort of straightforward. We put it in our motion. The essence of this is the Government has to show that there was an official request by a preponderance of the evidence. Of course, they said we did it, but you don't mail this in. We cited some cases -- the ***Wilson*** case -- and actually, the

Government cited the *Trainer* case, and they should be credited for it, because they got -- the Government got slapped around in *Trainer*. You just can't mail this one in. There are some formalities here. And, simply stated, you have to show that there was an official request, and they simply failed to do so. And what's interesting about this is --

THE COURT: And who do they have to show the official request to, --

MR. WEINGARTEN: The judge.

THE COURT: -- that there was --

MR. WEINGARTEN: The judge.

THE COURT: -- an official request?

MR. WEINGARTEN: The judge.

THE COURT: Okay.

MR. WEINGARTEN: And this is a formal proceeding. There is a treaty between the United States and China. That treaty called -- the treaty specifically calls for -- it places obligations on both parties. And when you're asking for information, you have to do five different things. We put it in our pleadings. And they didn't show the judge that they had done that. So, perforce, they have failed the simple obligation they have under 3292.

Now, what is most interesting about this to us is their explanation for why they didn't do so. And in their brief, they say, well, it's confidential, and sometimes there's

attorney-client information, and that's why we didn't show it to Judge Fitzwater. Excuse me? I mean, that one doesn't pass the laugh test. I mean, a United States District Court judge can't get information that they sent to unknown judicial authorities in China? I mean, that's simply preposterous, obviously.

And then they'll say, I'm sure, when they get up to the podium, that the reason was, well, it could have been public. Well, not if it's sealed. I mean, obviously, it seems like every other case in my life, I'm handling sensitive information, and certainly courts are used to handling sensitive information. I mean, the very idea that you can send, quote, sensitive information overseas to an unknown Chinese judicial authority and you're not prepared to do it to a U.S. District Court judge in this courthouse, frankly, doesn't pass the laugh test.

Now, they'll also say, well, by law, by the treaty, we have to deal with things confidentially, and I certainly, obviously, looked at the treaty. And the treaty says except as required by law. And obviously a judge taking a look at an application under 3292 fits under that category.

Let me say one more thing. And I want to be really clear on my language about this. I mean, I assume integrity and competence when I deal with U.S. prosecutors, and I certainly -- there's nothing that's happened in this case that suggests

otherwise here. But there is an interesting thing about this that is triggered by this explanation for why they didn't submit this information to Judge Fitzwater. In other cases, it's not unknown -- and I'm actually involved in one in the Northern District of California today -- there have been instances where prosecutors wanted to extend the statute of limitations and, you know, as a stratagem, or even as a gimmick, they've turned to 3292. I'm not suggesting that happened here, but what is apparent to us is, at the time they made the application to China, they had a boatload of evidence. They had conducted searches. They had conducted interviews. They had issued grand jury subpoenas. They had a ton of evidence. They were representing to defense counsel, I believe, that they were ready to go and indict people. Now, that doesn't mean they didn't have a legitimate interest in more evidence in China. But without knowing specifically what evidence they were seeking, what -- how were they going to use it, and they -- there are hints of this in the application.

THE COURT: Is there some requirement that that be shown as well?

MR. WEINGARTEN: To the judge, for sure. I mean, --

THE COURT: How they're --

MR. WEINGARTEN: Well, no, --

THE COURT: -- going to use it and whether they needed it and --

MR. WEINGARTEN: No, no. No.

THE COURT: -- whether they had a case without it?

MR. WEINGARTEN: What I'm suggesting --

THE COURT: Okay.

MR. WEINGARTEN: -- is if this -- and I'm not alleging this. But if this was simply a tactic to extend the statute of limitations and that was not disclosed to the judge, I mean, that would be a matter of interest to the District Court, I am sure.

And what is apparent to us is that they have a ton of evidence. I mean, what is it that they were after? And they indicate they were after an interview, and we assume it is of this man named Zhou, and if I've mispronounced his name, I apologize. Z -- I think it's Z-H-O-U. And they wanted to interview him.

What also has tickled our interest is it is apparent from the discovery that they well may have interviewed him already, or if not already, soon after their application. And that would be inconsistent with the representations that were made to the Court that the Chinese never responded to their request.

So all I am saying right now is if in fact this was simply a tactic to extend the statute of limitations, that would be of interest to the District Court, I am sure. I'm not alleging that. I am saying there are some peculiarities in the record, in our discovery. It seems as if the Government has

interviewed someone that they made representations that they wanted to interview, and at the same time made representations to the Court that they have been unsuccessful in getting the information.

I assume there's an utterly benign explanation for this, but what I also think is that we have shown enough sort of based upon the record that we should get our hands on the official application, not just the Court, to see if they have fulfilled the obligations of the treaty.

So, two points. One, I think they screwed up. I think they didn't show the judge what they needed to show the judge to make this application, and they should lose just on that. If they scrape past that, I think there should be some discovery, and I think the discovery, simply stated, should be an explanation as to whether or not they interviewed the person that they were seeking to interview. If so, why wasn't that reported to the Court? And let us see the application itself under any circumstances. I can't imagine what's in that application that is so sensitive that we can't see it. But then we can make a determination whether or not they fulfilled their obligations under the treaty.

Thank you, Your Honor.

THE COURT: Thank you.

MR. RUNKLE: Thank you, Your Honor.

THE COURT: Yes, sir.

MR. RUNKLE: Patrick Runkle for the Government. I'll try to be as brief as I can on this.

The major problem with Mr. Weingarten's arguments is that none of that is in the statute. The statute is very clear about what it requires. The definition of official request in the statute, and this is a very important point, is the statute's definition of official request does not limit an official request to a written request. And so their position that if it's a written request it has to be filed with the Court or that all requests have to be filed with the Court, I think that Congress had a more capacious view of what it was doing with this statute, which is that any time a request is made to a foreign governments for assistance with legal -- with a criminal investigation, that if the Government presents by a preponderance of the evidence to a district judge that that request was sent or made, then the district judge is -- shall enter an order tolling the statute of limitations.

Now, I do want to respond to Mr. Weingarten's pragmatic argument about why this was done. I'm not aware of any interview with Vincent Zhou in China. I think that would come as a huge shock to all of the people on this side of the room. So I can make the representation that I have never interviewed Vincent Zhou in China, nor have any of the agents on this case done so, and if the --

THE COURT: I think what he meant was that maybe there

was a suggestion that the request was that he be interviewed.

MR. RUNKLE: That is the request.

THE COURT: Yes.

MR. RUNKLE: That's absolutely the request.

THE COURT: Okay.

MR. RUNKLE: But Mr. Weingarten said there was evidence in the discovery that he had already been interviewed. That hasn't occurred.

But in addition to that, I want to respond to the pragmatic argument, since it's been made, that this was some sort of a gimmick to try to extend the statute of limitations. What actually happened was that we had a meeting here in Dallas in August 2014 with USPLabs' prior corporate counsel, Peter Barton Hunt. And Peter Barton Hunt told us during that meeting -- that meeting, we were mostly interested at that point in the case in the aegeline conduct -- but Peter Barton Hunt told us during that meeting that USPLabs had never passed off its DMAA as a geranium extract in marketing or in labeling or in its promotional materials. And after that meeting, we investigated those claims and we decided, you know, we determined that they weren't true and that Peter Barton Hunt had told us things that were not accurate during that meeting. And so our focus of the investigation shifted at that point, and that's why there was a completely legitimate reason at that point where we realized that we needed more information from China and that's why we

sought it.

So I just wanted to respond that, that this was -- this is entirely permitted by the statutes. It's entirely permitted by the course -- when the course of investigation takes that kind of a turn and the evidence is outside of the country, that's the risk that a potential defendant takes by conspiring with people outside the country, that there could be as much as a three-year extension of the statute of limitations.

And I would rest on my papers. Thank you, Your Honor.

MR. WEINGARTEN: Two quick points, if I may, Your Honor.

THE COURT: Yes.

MR. WEINGARTEN: Simply this. And it's just, it's a matter of statutory interpretation. There are different ways you can make a request for information, and I'm looking at 3292(d), and it says, "As used in this section, the term official request means a letter rogatory, a request under a treaty or convention, or any other requests for evidence made by a court of the United States or an authority" -- blah, blah, blah.

The point is they chose the treaty method. That's what they used. That's what was required between China and the United States. Once you make that selection, you can't say, oh, oh, I'll call Uncle Joe, the sheriff of Beijing. I mean, that's crazy. That's -- I mean, can you imagine if a DEA agent

said, I'm going to call Uncle Joe in Beijing, and that would be sufficient to toll the statute of limitations? There's a formal treaty between the United States and China. That's what they chose to use. Once they made that choice, they have to follow it. And there's no evidence that they did, not by a preponderance or any other standard. And that's why they screwed up and they need to pay the penalty.

And the other point, I don't believe I said I thought there was an interview in China. I mean, the discovery piece that we have suggests -- and I pulled it out and I want to be precise on it -- is that in October of 2015 -- this would have been a couple of months later -- there may well have been a meeting with Mr. Zhou here or in the United States with law enforcement officials. That would be useful to know, on how did that happen? I mean, did the Chinese -- it's inconceivable to me that the prosecutors deliberately misled the Court when they made the application. I can't imagine that that's the case. Or that the OIA lawyer, when he reported to the Court on the failure of the Chinese to respond, made intentional misstatements. But what we have is the possibility. And if the prosecutors say it never happened, it never happened. We're fine with that. But that's why we're raising the possibility that this really was an effort to toll the statute, with no particular interest in the evidence sought because they were getting the evidence informally and through a variety of

different ways.

THE COURT: Why can't this Court, though, just request that the documents be produced or the requests be produced for *in camera* inspection?

MR. WEINGARTEN: Of course you could. My suggestion would be that we see it, too. I mean, we're responsible officers --

THE COURT: Well, *in camera* means you don't.

MR. WEINGARTEN: I didn't realize that, Your Honor.

(Laughter.)

MR. WEINGARTEN: Can I just make one more observation on this?

THE COURT: Yes.

MR. WEINGARTEN: Look. We're officers of the Court. I mean, it's hard to believe that what's contained in that document is anything different substantively --

THE COURT: But if your concern and the basis of your motion is that the request wasn't made, and the Court reviews to determine, make that determination, then --

MR. WEINGARTEN: Well, no, I think it's slightly different. I mean, I -- look. If they say they made the official request, I don't disbelieve them. That's not what I'm saying. They didn't show it to the Court.

THE COURT: Okay.

MR. WEINGARTEN: I mean, they screwed up.

THE COURT: So then your argument boils down to whether or not the technical requirements of the statute are met?

MR. WEINGARTEN: No, well, it -- I also think that if they didn't meet the requirements of the treaty, I mean, if they failed to meet the five obligations they have under the treaty, and I think, respectfully, we would be in the best position because of our familiarity with the investigation, I think that has consequences, too.

THE COURT: But doesn't it say that that consequence is not to suppress or exclude any evidence? Am I looking at the wrong thing? The MLAA?

MR. WEINGARTEN: I'm drawing a blank, Your Honor. I apologize. I'm not sure what you're making reference to.

THE COURT: I know I read that somewhere. Okay. Don't let me hold you up, though.

MR. WEINGARTEN: No, I mean, I guess -- I mean, I -- and I would be extremely surprised if the prosecutors were, you know, sort of playing with words here, too. If they had absolutely no contact with Mr. Zhou, the last piece that I suggested goes out the window.

I mean, the real issue would be if this really was just a stratagem or a tactic to extend the statute with no interest in the evidence. I think us taking a look at the official request -- let's say the official request requests evidence that they

already have, I mean, or they could easily get. I mean, in their papers they suggest one of the reasons we want to -- you know, obviously, in their search warrants, --

THE COURT: I just don't understand the authority, though, for you actually looking at their official request, no more than them being able to look at *ex parte* subpoenas issued on your behalf. Why would you get to look at that?

MR. WEINGARTEN: I think we would have to make a good faith basis that this was all just a tactic.

THE COURT: But it wouldn't be your decision; it would be the Court's decision, right?

MR. WEINGARTEN: No, of course. Of course.

THE COURT: So, then, again, we're back to why couldn't I look at it?

MR. WEINGARTEN: Of course. I'm just trying to be helpful.

THE COURT: Okay. Yes?

MR. RUNKLE: Just a --

THE COURT: It's his motion, though. If you want to say something else and he wants to respond to it, I'm going to let him.

MR. RUNKLE: Well, there's a practical problem in that the document is a very lengthy document in Mandarin Chinese.

THE COURT: Okay.

MR. RUNKLE: So, you know, if Judge Fitzwater had seen

it, I know Judge Fitzwater is a very esteemed and learned jurist, but I have doubts that he would be able to read a 30-page Chinese document. It would have to be translated. I think that's part of the concern here.

And I wanted to respond to something Mr. Weingarten said earlier, which was that the discussion in the motion about whether these requests are routinely filed with courts, that is -- that, as far as I understand, that is from OIA policy. That's the Office of International Affairs. That is what I was told. That is their standard position.

I don't doubt that in other cases Mr. Weingarten has been involved in that that position has been varied. I wouldn't doubt what he says. But that argument was not intended to deceive or to be -- not be forthright. That is the position of OIA about filing these requests, even sealed on court dockets. I had a discussion about this. They said that there's a concern that even if it's sealed on a court docket, that, over time, there -- the more of these requests that become public, there's an international relations concern. I have no idea. You know, that is above my pay grade. I don't know what the exact basis of that is, but that's the position that they take. So I wanted to explain that to the Court.

THE COURT: Thank you.

MR. WEINGARTEN: Just one more thing. Look, again, I don't want to fight with these guys more than I have to, but

the idea that the only thing available is a 30-page Mandarin document: somebody wrote it in English before it had to get translated. I mean, that's -- with due respect, that's crazy. That can't rule the day.

THE COURT: Anything further on that?

MR. RUNKLE: What I would say is that the part that --

THE COURT: Not from you. From other -- any other defense counsel. Of course, I'm assuming you join in.

MR. GIBSON: Yes, Your Honor. I think, on behalf of Jacob Geissler, we join in and we do maybe ask, even if it's in Mandarin, Chinese, or what, that as part of the Court's order here, ask the Government to produce *in camera* for this Court's review any of those documents submitted for the application, and that the Court make a determination or decision whether we can be seeing or not, or whether it's relevant to some other aspect of this case or motions that the Court will hear.

THE COURT: Thank you, sir. Anybody else want to add something? Okay. I don't see anybody else moving quickly to the microphone. So why don't we go ahead and look at the arguments regarding Count 7?

MR. WEINGARTEN: Me again, Your Honor.

THE COURT: I'm making you earn that --

MR. WEINGARTEN: So, this one is -- the issue is simple, and it comes down to this. There's really just one quirk. Can shipping documents be labeling? In other words,

can documents that describe ingredients that are shipped I think almost entirely from China to the United States constitute labeling for a misbranding charge that we find at Count 7?

And, interestingly, I mean, the prosecutors in Count 7 charge that the purpose of the misbranding was to mislead law enforcement as to what was actually being shipped in. And, I mean, that just reinforces our notion that whatever these COAs are, whatever issues we have with these importation documents, they're not labels. It's not labeling. And I think they have mightily tried to dance around that in their pleading and suggest that somehow these shipping documents, the documents that describe the ingredients from overseas, found their way into end products that were used by consumers and therefore it's labeling. But that's not what they were thinking when they charged this, and of course, the Court's responsibility this minute is to determine whether or not Count 7 passes muster.

Now, let's start with common sense. I mean, to the extent people know what labeling is, both in the world and in an FDA sense, I mean, obviously what we think of is what's on the bottle and what the pharmacist throws into the bag when you buy your drugs. In truth and in fact, there are a million cases -- I'm exaggerating, but not by much -- that labeling is essentially marketing and advertising, and the purpose of the

misbranding statute is to protect purchasers to whom the claims are addressed. With all due respect, that ain't shipping documents.

And there's another piece to this. Labeling is intended to provide substantial information about the use and benefits of the article to the people who are going to use it. And again, that ain't shipping documents.

And I know and I'm sure we're about to hear there are cases that suggest that labeling under the law is a little broader than that, but sort of the mainstream here is labeling is marketing and advertising document, lightyears from where we are in this count.

So what -- we also get some guidance from Judge Lindsay. By coincidence, he wrote a long decision about what labeling is and isn't in *Hanafy*. He was affirmed in *Hanafy*, too. Those documents -- those cases are obviously available to all sides. We've read them. Judge Lindsay provides a thoughtful history on the subject. And, you know, his ruling -- shipping trays are not labels or labeling under the law -- you know, it's not directly relevant to here, but I think it's useful.

And what is true is no case that we have found, we're not FDA lawyers, but no case that we have found suggested, established, or ruled that shipping documents are labeling documents for purposes of the misbranding statute.

It's -- you know, and the prosecutors will say, well, how

can it be that if you falsify your shipping documents you get a pass under the law that it's not labeling? And the obvious answer: There are any number of general fraud statutes or 1001 kind of statutes or Customs-related regs that can be translated into Title 18 offenses that could have been used if they believed they had a case for the shipping documents. And that's not what was used here. They used the misbranding statute that just simply has no application.

A lot of discussion in the briefing about materiality, whether or not it's an element. I don't think we need to focus on that unless the Court wants to. I mean, one of the ironic things about this in terms of the misbranding -- the purpose of the misbranding protections is to protect consumers from misinformation on the labeling. And obviously, as the Court understands, and it goes to the materiality argument but it's a relevant fact as well, is that the ingredients that were being shipped from China were going to USPLabs. So it's a fair inference that they were not defrauded by the COAs at issue in this case.

I mean, the bottom line, Judge, whatever issues the Defendants have in this case with the shipping documents, they're not labeling documents and Count 7 should fall.

MR. RUNKLE: Thank you, Your Honor. The first thing I would say is that I think we heard a slightly different argument today than is in the motion that the Defendants

presented. The idea that shipping documents are never labeling I think was decided by the Supreme Court in the ***Kordel v. United States*** case, and what I took the motion to say was that in this case the shipping documents are not labeling because the product is not reaching end consumers, that that's the additional thing that they're trying to add to the labeling statute.

I think the Defendants' attempts to shoehorn this case into ***Hanafy*** are misplaced. ***Hanafy*** was about whether the tray conveyed substantial information. I don't think the Defendants actually dispute that these documents, in addition to the actual labeling on the drums that came from China, and I think that's one of the things Mr. Weingarten is missing, is that not only did these -- did the shipping documents contain these false names; also, the labeling on the drums that came from China, the actual labeling on the drums.

I think the other important distinction that Mr. Weingarten is missing is the idea that, for purposes of ingredients under the Food, Drug, and Cosmetic Act, the end consumer of an ingredient shipment is in fact the manufacturer who's going to use that ingredient shipment to make a product. And obviously it's a fungible commodity, and an ingredient shipment needs to be properly labeled in case it ends up in a different manufacturer or if it -- in case it ends up in the warehouse and somebody who isn't part of the fraud scheme is unaware of

what it is and puts it in the wrong tub when they're mixing ingredients. It's obvious how that could easily lead to a very serious public health concern.

The last point I would make is that the Fifth Circuit essentially rejected this exact argument 65 years ago in the ***Otis McAllister*** case. That case was about adulteration of ingredients, but you would think ***Otis Mcallister*** would have to have come out differently if the argument that the Defense is making is correct, because ***Otis McAllister*** was about an adulterated ingredient shipment of green coffee beans that could not be eaten by consumers, and the argument was FDA didn't have any jurisdiction over it because we have to process it and we'll take care of whatever the problem is with it before it reaches the consumer. The Fifth Circuit said that wasn't right, that the FDA had jurisdiction over it because it's an adulterated ingredient and met the statutory terms.

Here, we obviously have labeling under the statutory terms, and we meet those terms and the indictment is sufficient. Thank you, Your Honor.

THE COURT: Anything in rebuttal argument, sir?

MR. WEINGARTEN: Yeah, I mean, it's -- there are a lot of cases -- I'm sure the Court knows there are a lot of cases on what labeling is and what labeling is not. And a lot of them are modern cases. And to a case, what is described is the advertising and teaching piece to people who buy products. And

the Government has an array -- they just charged this wrong if what they're concerned about are shipping documents.

THE COURT: What about his argument, though, that the end user is actually the manufacturer rather than the consumer, ultimate consumer of the product?

MR. WEINGARTEN: Just it's what's labeling, and it -- to us, you have a Chinese manufacturer and he puts the wrong thing on a tray or whatever and ships it across the sea and somewhere down the road it gets -- someone goes into a pharmacy ten steps later and buys a product with that in it.

THE COURT: No, no. You're missing what I'm asking you. What I'm asking you is what about his argument that the person who receives the raw ingredient that's allegedly mislabeled is actually the consumer?

MR. WEINGARTEN: Well, but that's USPLabs. I mean, the irony of this, they ordered this stuff. And if there was some misbehavior between China and USPLabs, that's a different issue. It's just not labeling. Okay.

THE COURT: Thank you.

MR. WEINGARTEN: Sure.

THE COURT: Any other defense counsel want to weigh in on this particular motion? Why don't we look at the two misdemeanor counts, arguments regarding Counts 9 and 10?

MR. WEINGARTEN: If I could make a suggestion, Judge. So, the misdemeanor counts are 220 and 221. Oh, I'm sorry, 221

is the misdemeanor count. 220 is the attack on the sufficiency of Count 10. I'm happy to do them -- I mean, they're completely interrelated, --

THE COURT: Okay.

MR. WEINGARTEN: -- and, if the Court wishes, I can do both.

THE COURT: Yes.

MR. WEINGARTEN: Okay. So, Judge, on this one, so, you know, I'm a basketball nut, I'm watching the playoffs last night, but I can't help but focus on the ***Daubert*** hearing and the impression it made on me. And I had two profound reactions to it, and they both start -- and they're all about Count 10. They're all about this misdemeanor. And, of course, Count 9, too.

And I start with this idea. We are talking about a misdemeanor. We're in criminal court. We're talking about a strict liability misdemeanor. We're talking about a misdemeanor that could put someone in prison for a year. And we're talking about a charge that doesn't require criminal intent, doesn't require ***scienter*** of any kind, and good faith is not a defense. And, you know, there's -- and it comes out of the ***Park*** doctrine. You know, we informally call ***Park*** the rat food case. It's, you know, 1975. It's a Baltimore warehouse, and they store food, and there's rat poop everywhere. And the CEO had -- no evidence that the CEO knows about it, but it's

such an appalling situation that we have the *Park* doctrine, and that's the law. That's the Supreme -- it's a Supreme Court decision that's not been overruled. Okay. Just allow me a 30-second indulgence here.

I recently had a trial almost two years ago in Boston on the *Park* -- partly on the *Park* doctrine. I represented a CEO named Bill Facteau from a company called Acclarent, a medical device company involving sinuses. I'm sure these guys know the case. It was tried in Boston. They charged him with a bunch of felonies, and it was largely about off-label promotion. And the issue was, he's the CEO, he runs the company, and he had salesman all over the world who were selling the thing, and the allegations were that there was off-label promotion, that they were promoting the device for sinuses for different things that were not cleared by the FDA. Charged with a ton of felonies and some misdemeanors. And the misdemeanors were the strict liability. Responsible corporate officer, on your watch. And Acclarent was a big company. I mean, it had salesmen everywhere.

The evidence at trial was that my client knew nothing about the off-label promotion, did everything a competent, responsible CEO would have done to make his salesmen comply with the rules, and at the end of the day they acquitted him of all the felonies and convicted him of the misdemeanors because of the *Park* doctrine. You know, he was in a position of

responsibility. The salesmen did promote off-label. And, you know, I can't remember if it's eight misdemeanors or ten misdemeanors. And, you know, they could be stacked.

Now, interestingly enough, Judge Burroughs -- Allison Burroughs was the judge. Almost two years later -- of course, we attacked *Park* every way you can attack *Park*. And she hasn't ruled on the motion -- she hasn't -- we've not gotten to sentencing, almost two years later. I have no idea what's going on in her chambers, but based upon body chemistry, you know, I'm sure -- I think she -- look, it just felt wrong that you have a criminal penalty of up to a year that could be stacked if there's more than one misdemeanor and somebody can go down doing nothing wrong. It felt wrong in the courtroom. Now, --

THE COURT: But if *Park* says that and *Park* is from the Supreme Court and you are arguing this here, you don't expect that --

MR. WEINGARTEN: I don't.

THE COURT: -- we're going to --

MR. WEINGARTEN: No, I don't.

THE COURT: -- do something different here?

MR. WEINGARTEN: No, no.

THE COURT: You're just reserving it so that you can eventually make your way to the Supreme Court and make that argument?

MR. WEINGARTEN: Well, the reason I'm talking to you about Boston, I don't expect you to say, oh, the Supreme Court, Warren Burger was full of it, I'm overturning *Park*. I don't expect that. But I think Judge Burroughs well may, in an indirect way.

Now, what's true about *Park*, nobody back then argued void for vagueness. So, I mean, that argument has not been made. And of course, we made it in Boston. And boy, would I love to see a decision come down in Boston before anybody goes to trial here.

But I just tell you that, as a visceral matter, and I thank you for indulging me, in court, like as a defense attorney with a human being to my left, the idea of someone being convicted and prosecutors wanting him to go to jail when there's no evidence he did anything wrong just struck me profoundly as not what's right in the world.

Okay. Number two, listening yesterday, Judge, the -- you know, the guy from the FDA, I thought highly motivated and admirable person. I thought the world is better that he's in it, you know, solving all these outbreaks than if he's not in it. But understand full well, I mean, it is going to be a ground war about what happened in Hawaii. I mean, we have a completely different version. We believe many of the people who got sick had other illnesses that caused their sickness. I mean, each -- I mean, there's going to be a ground war in this.

And, you know, you've seen -- you've seen our exhibits. You saw -- I mean, Covington & Burling is a very serious law firm, and they represented USPLabs and they made a big submission about Hawaii to the FDA. And, you know, maybe part of it will be challenged. Maybe -- who knows? But there is another side to this story.

The point to this, this strict liability misdemeanor will move a two-week trial to a two-month trial, at a minimum. I mean, I do trials. I know how these things work. And if there's the ground war that I expect there to be about Hawaii, there's -- it just changes the world. And as I was watching my Celtics, it seemed preposterous that a strict liability misdemeanor will be the trigger to that.

Okay. Now let's get to the meat, let's get to void for vagueness, because obviously that's our primary thrust for the attacks on Count 9 and 10. And, again, with ***Park***, it's important to know that no -- the Supreme Court did not rule on void for vagueness for a strict liability misdemeanor. What is true is -- and I know the Court has read all the cases, and it is well-briefed, and I again commend the Government. Their briefs are thoughtful and well-researched.

The Supremes are busy with -- and I don't say that disrespectfully. The Supreme Court is busy with void for vagueness as we speak. Just a couple of weeks ago, they came out with ***Sessions v. Dimaya***. It's a -- to the extent you like

to read this stuff, it's an interesting decision. And they found a statute involving how you throw somebody -- you know what I'm talking about. And I think what it does, I mean, two things interesting about this. You know, we scuffled about what *Johnson* meant and, you know, this explains it. So we -- I think the *Johnson* issue is resolved.

What's also true to me, you know, Elena Kagan wrote the opinion, and joined by Neil Gorsuch. So, in this one, strange bedfellows. So, I mean, the importance to me is the Supreme Court is very sensitive about void for vagueness. The Court obviously is familiar with this.

I think the most useful place to go in terms of this argument right this minute is to the Fifth Circuit. And what we tried to do is look at the Fifth Circuit cases, the relevant Fifth Circuit cases, that were interested and concerned about void for vagueness and compile a list of factors. And this is, you know, void for vagueness to a statute as applied. And, you know, we list the statutes in our brief, and we came up with four.

And, one, whether the statue at issue is an economic regulation. Meaning, the party can seek clarification, go back to the agency.

Number two, notice. How much notice does the party have as to what the -- whether or not the conduct was proscribed?

Three, is there *scienter*? You have to have some knowledge.

And four, obviously, the most important, is it criminal or civil?

And you know, that's -- I think it's a -- we made an effort to come up with a responsible list, and I think we've succeeded.

Now, how does that apply to Count 9 and Count 10? And obviously, for Count 9, we're talking misbranding, false and misleading, it being the issue. And at the center of Count 9, of course, is the term extract. And you know, obviously, I know you've read our briefs, and the issue is what is an extract under the law? And simply stated, I mean, there's no definition. And obviously, in the regs, in our briefs and the Government's brief, the FDA thinks about extracts and what they are, but there is no definition for a normal human being to rely on when trying to conform with the law. No definition anywhere.

Obviously, you know, we say: what we had with the cynanchum was an extract. It was an aqueous extract. And obviously my friends over here are going to say, well, that's -- well, that's -- well, we fight that out in court, whether or not it was an aqueous extract. That's for the jury to decide. So, and on that instance, they are probably right. But the question is, who's to say what's an extract for purposes of conforming your conduct to the law? And if you guess wrong, you go to jail? Is that where the law is here?

On #10, on the adulteration count, obviously, you read a lot about what we say about significant and unreasonable risk of illness or injury. And so we point out everywhere we can that the FDA has an entirely logical, wholesome, professional way of establishing whether or not a supplement is adulterated. They obviously chose not to use it here. I don't know, as a matter of law, in 2018, they're obliged to do so before they charge somebody, but obviously, as a matter of public policy, it's a good thing, and obviously it would have avoided a lot of trouble here.

We point out in our exhibits, and I think it's important for the Court to review them, I'm sure you have, that on aegeline, which is the subject matter of Count 10, I mean, there are -- I think there are at least half a dozen exhibits that we attach to our brief where it is apparent that the FDA itself decides this, the professionals. The agency with responsibility on this issue did not -- they were not sure whether or not the -- whether or not aegeline was an adulterated product or the extent of the danger of aegeline. If they weren't sure, the responsibility was upon us to make a judgment that we were in violation of the law? I mean, that cannot make sense.

So what I -- I think the sensible thing to do is to go back to the four-part test that we started with from the Fifth Circuit and ask the questions for both 9 and 10. And I think

it's a useful exercise, and I think we win on all four.

And the first, of course, is whether or not the statute at issue is an economic reg so a party may seek clarification. And it's not. It's a criminal statute. We wish it were an economic reg. It would have -- that would have been the ideal situation. So, you know, we're bringing the stuff in. It's interesting. It has a good effect on bodybuilders. Mr. FDA, what's up? Can we use this stuff or not? That would seem to make sense. And if the FDA said no and then they peddled the stuff out the back door, then you go to jail. Not if you make a judgment with absolutely no clarification or guidance from any regulatory body.

Amount of notice, none in this instance, that an extract was some particular definition from the F -- none.

Number 3, *scienter* requirement. Obviously, not. That's where I started.

And obviously, this is a criminal statute that holds the that possibility of prison.

So I think a fair reading of the law in the Fifth Circuit causes one to seriously believe that there's a problem here. I mean, the combination of the -- of strict liability misdemeanor with absolutely no guidance as to how to behave in these particular instances creates serious problems.

The problems are reinforced or doubled or tripled or quadrupled by how the charges were brought. In particular,

Count 10. I mean, Count -- to call Count 10 vague is to sort of overstate it. And this is, of course, the adulteration charge. And for all intents and purposes, they say one thing: that the aegeline-related products were associated with the outbreak, pure and simple, and that, they maintain, is sufficient to charge a defendant or defendants with a criminal offense. It's I think not even close. No causal link. No indication of how it's associated. It's deliberately vague.

Now, I mean, there are a million cases I know that say you can track the indictment, just have to put in a few things here and there.

THE COURT: Track the statute?

MR. WEINGARTEN: Say again?

THE COURT: Track the statute?

MR. WEINGARTEN: Track -- that's right. Of course. Track the statute. But there are cases that say otherwise. We put them in our brief. I don't think they come close to stating an offense for Count 10.

And it's -- it is -- it's not unknown for a court to toss a count or two or an indictment for failure to state an offense. As I was reading cases while watching the game last night, I saw two in our compilation that I actually argued. There were two cases in this circuit where District Court judges either threw out the entire indictment or part of the indictment. One is ***U.S. v. Kay***. It was a case in Houston, and Judge Hittner

tossed the indictment. And one was ***U.S. v. Rainey.*** That was in New Orleans. That was sort of the ***BP*** case. And the judge tossed part of the indictment for purposes of -- and I was the lead lawyer in the both, which I didn't even realize we had cited those cases, but we did. And for purposes of full disclosure, the Fifth Circuit in each instance had something to say about it and there were trials. But the point of all this is they have an obligation. You just simply can't track the statute. And in this instance, simply to say aegeline-related products are associated with an outbreak and say nothing more doesn't get you close.

So I think there's a sort of three-part thing going on here. You have this overall problem with the strict liability misdemeanor. You have the void for vagueness argument as applied to the understanding, words and in the statute. And then on top of that you have an indictment that is drafted in a way that it actually doesn't state an offense. I think 10 goes, Your Honor. And I think it would have a salutary -- a profoundly salutary effect on the rest of the charges.

MR. RUNKLE: Just a few points, Your Honor. One thing I think is covered in the papers but I think, given Mr. Weingarten's arguments, I need to reemphasize it, is that in this case we barely even get to the ***Park*** doctrine. The allegations in Counts 9 and 10 are that the Defendants themselves -- ***Park*** is a different species of liability. The

allegations are that the Defendants themselves participated in the acts that resulted in the misbranding and adulteration. So USPLabs had an interesting corporate structure where the CEO, Mr. Geissler, and his partner, Mr. Doyle, Mr. Hebert, they personally participated in the creation of these products. So when we're talking about the *Park* case and the Acme warehouse and the rat poo, *Park* is about how that CEO actually had no knowledge about that situation. Here, we have a very different situation where it's a misdemeanor where the Defendants themselves participated in those acts. And I think *Park* recognizes that as a different species of liability than the one where you're applying a strict liability responsible corporate officer doctrine.

In addition, we would -- you know, that's a fallback position, that, you know, that they are strictly liable, but there also is evidence that they personally participated in the misbranding and the adulterations in Counts 9 and 10.

In terms of constitutional vagueness, I would just rely on the statement from the *Johnson* case where the Court said very clearly that they don't doubt the constitutionality of laws, and they use the exact phrase from -- that is in a number of laws, including this one, about substantial risk and that they don't doubt the constitutionality of that.

In terms of the -- in terms of Count 10 kind of taking over the rest of the case, I think Count 10, the dispute over the

liver injuries in Hawaii is also, as explained yesterday, involved in Count 1. It's also involved in Count 6. And I believe that we will be able to not have a full-on ground war over in Judge Lindsay's courtroom about Hawaii. But I don't think that that really has anything to do with whether Count 10 is sufficient.

I won't recite to Your Honor all the cases about how tracking language of the statute is sufficient. Here, the leading guidance, including the Tenth Circuit's opinion in *Nutraceuticals v. Von Eschenbach*, says that under the statute, you know, we do a risk-benefit analysis. The FDA's statements in the ephedra matter are that the government doesn't even need to prove probable cause or that a product caused any specific injury in order to present the type of risk that Congress was talking about under the statute. Of course, that would be a perverse incentive to put out untested products because you have to wait for someone to actually be injured in order to enforce the law, and I think that's not what Congress intended.

Just a couple other minor points. Mr. Weingarten asked: if the agency can't figure it out, whose responsibility is it to figure out that -- how to comply with the law? I think that, you know, the better part of a century of case law says, under the FDCA, it is the company's responsibility to ensure that its products are safe. And if it's an untested product or if it's a product that could cause the types of horrifying

injuries that we've seen in this case, it actually is on them to make sure that the product is safe, despite -- no matter what the agency is doing at the time. Nobody asked the agency to figure out prospectively whether OxyElite Pro new formula was safe. They just put it on the market. That's their responsibility under the FDCA.

And finally, I'd just point out that the indictment, under the case law that we cited in our briefs, the indictment can be amplified by notice that's provided throughout the litigation, and I think they have -- they have very, very ample notice given, the disclosures that we filed and the expert disclosures last May of exactly what types of risk we believe this product caused. I mean, I'm sorry, what types of risk this product presented to consumers and how we intend to prove that.

Thank you, Your Honor.

THE COURT: Anything further, sir, in rebuttal?

MR. WEINGARTEN: I don't think so.

THE COURT: Does either defense counsel want to chime in on this?

Count 7? Have we talked about 6 and 7?

MR. WEINGARTEN: Judge, I think there are two more. It's 5, 8, and 9 is one, and then there's 6.

THE COURT: Okay.

MR. WEINGARTEN: And if I can suggest that --

THE COURT: Yes. Okay.

MR. WEINGARTEN: -- that we do 5, 8, and 9 now.

THE COURT: Document 383, which is the -- Document 383, which is the motion to dismiss Counts 5 and 8 through 9. And then there's also Document 387, the obstruction of agency proceeding, Count 6.

MR. FRAGALE: Good morning, Your Honor. David Fragale representing USPLabs.

These counts actually involve a third party we haven't -- a third product we haven't heard much about. OxyElite Pro Advanced Formula. Counts 5, 8, and 9 are premised on the allegations that USPLabs falsely stated that OEP Advanced Formula, OEPAF, contains cynanchum auriculatum root extract, and --

THE COURT: Pronounce that again for me.

MR. FRAGALE: I don't think I can. Cynanchum auriculatum root extract. Four words. When in fact it did not. The hole in the indictment rests upon some unstated definition of the term cynanchum root extract or extract generally, which is the standard upon which the jury would consider whether the label was false.

In fact, when we look at the indictment in the Government's opposition to our motion, it becomes clear that convictions on Counts 5, 8, and 9 would require a conflation of three terms with three different meanings: a cynanchum auriculatum root extract, ethanol extract, and extract.

For example, if we look at Paragraph 49 -- I'm sorry, 41(b) in the indictment, it states, "In the case of cynanchum auriculatum, the co-conspirators made and caused to be made misleading statements, such as the following advertisement directed at the public. Cynanchum auriculatum root extract, which is what's on the product label, it says, 'This herb is native to an Asian temperate and tropical region such as China and Nepal. It's long been used as food and for a variety of purposes by those in these regions.'"

Next paragraph. "'More recently, ethanol extracts derived from the roots this herb have been studied both *in vitro* and *in vivo*, producing exciting emerging data.'"

The company did not say extracts derived from the roots of this herb. It says ethanol extracts, and it -- not once did it put on its label that it had, in fact, an ethanol extract as the product.

THE COURT: Why isn't that a factual issue, though, for the jury?

MR. FRAGALE: Ultimately, the issue is going to be what is an extract, and I don't think the jury can both decide what this --

THE COURT: That's a little different from what you just argued, because you argued that they're not going to even be able to prove that that representation was made. Right?

MR. FRAGALE: Well, no, they will -- they will prove

-- there's two different things going on here. They -- no one denies that the statement on the website referred to two different things, the cynanchum root extract, which is what's on the label, --

THE COURT: Right.

MR. FRAGALE: -- and an ethanol extract, which is what's in the study that they're referring to about emerging data, which is not the product.

THE COURT: Right.

MR. FRAGALE: Right. And that's fine. They -- but the point is the Government is saying that we put on the label cynanchum auriculatum root extract and therefore it's not an extract and that's mislabeling. The problem is, there's different extracts. There's an ethanol extract which the company decided not to use because they determined that the extract using that process had too much toxicity. Instead, they decided to use a water extract which only removed mostly impurities, got rid of the stems, and used that in the product, which was much safer.

And so now the jury is going to have to decide, is cynanchum auriculatum root extract in fact an extract? Of course it's not an ethanol extract, but we never claim on the label that it is. So how is the jury going to decide whether what's actually on the label, what is actually in the product, falls under the definition of extract?

And you can see that the Government itself gets confused because when they write in their motion -- or, in their opposition --

THE COURT: So you're not conceding that it's an extract but not a alcohol extract?

MR. FRAGALE: It is absolutely an extract. It's not an ethanol extract.

THE COURT: Right.

MR. FRAGALE: Which --

THE COURT: So, then why are we talking about extract?

MR. FRAGALE: Because that -- because here's why. Because the Government notes in its opposition that Defendants once again argue that the substance they put into OEPAF was an extract. And that's the issue. Was it or was it not an extract?

THE COURT: Uh-huh.

MR. FRAGALE: Was the auriculatum root extract, does it fall under the definition of extract? And I think they're using the piece in that promotional material which is talking about a different process that has emerging data and saying, well, it's supposed to be an ethanol extract. You guys didn't use an ethanol extract. Therefore, it's mislabeled.

THE COURT: So doesn't that take us all the way back to this is a factual issue?

MR. FRAGALE: I don't think the jury gets to decide

the standard upon which to determine whether or not a false statement was made and also decide whether that statement was false. I think it's a question of the Court is going to have to decide what in fact is an extract. And we've said in the -- because the Government doesn't include one in the indictment. But certainly I think the Government -- the Court, if this goes to trial, would have to instruct the jury, this is what an extract is. Now you decide whether or not that label is false based on that definition.

I don't think the jury gets to decide -- for example, in a duty to disclose case, the Government can argue that a CEO has a duty to disclose, he failed to do so, therefore he violated the statute. In those cases, we would argue, well, where's the duty to disclose? What regulation says you have a duty to disclose? The jury doesn't get to make that determination. The Court does. And then the jury takes the next step and says, okay, if in fact there is a duty to disclose, did the CEO meet that obligation? And because the indictment is void on the question as to what the proper standard is, it fails to contain allegations that would suffice for a conviction.

THE COURT: Mr. Webster?

MR. WEBSTER: Your Honor, I've got a companion motion.

THE COURT: Come on up.

MR. WEBSTER: 394.

THE COURT: Come on up.

MR. WEBSTER: Thank you, Your Honor.

THE COURT: After we started talking, I realized I hadn't mentioned 394, but I do have it on my list here.

MR. WEBSTER: Thank you, Your Honor. There is some risk in following Eastern-educated smart fellows, Your Honor. I'll try not to embarrass the district in my argument.

But I do feel compelled to argue for Cy Willson. He is charged in Count 5 only, Your Honor. And it is the issue of what is an extract, and it is easier to imagine in the context of Cy Willson's allegation in Count 5. An indictment should be, if Rule 7 is followed, a plain, concise, and definite statement of all the essential facts necessary to charge an individual. The essential fact that we've got at play here is, of course, what is an extract? Again, not defined, as Mr. Fragale points out, not defined in the indictment.

We are going to be left stepping forward at the time of striking -- or, at the time of instructing the jury with the elements of the offense. No question about what the elements of mail fraud is. The fourth element, of course, being that there is in fact a material, false representation that forms the basis of the fraud. Here, the false representation is focused on the issue of extract.

As I point out in the brief, there is no proper definition, not only not in the indictment, there's no proper definition in the Federal -- Code of Federal Regulations. There's two failed

attempts by the FDA to define extract. We can go with the Merriam Webster's collegiate dictionary definition, which is not unusual. It is of very little help. It essentially states that an extract, either by -- by any kind of solvent, water, ethanol, or otherwise, if it reduces things to various components, a fracture of which, it is an extract. Water can be used to extract not only what it takes away with the water but what it also leaves. Both elements of that process are extracts.

That is not recognized by the Government. To the contrary, it recognizes that this is in fact -- I think they state it, they call it washing in their response. The footnote to the Government's response, it's Footnote 1 to their Document 416, states, Moreover, washing pulverized root powder with water, which is what the Defendants may have done, is not the same as using water as a solvent to extract compounds from powder. Their words. The latter obtains an extract; the former obtains a cleaner plant material.

There's no citation or authority for the basis of that conclusion. What we are left with then, at the time the jury gets this case, is the standard definition, the standard elements of mail fraud, but when we get to Element 4, we're going to have the possibility, the range of possibilities of a Merriam dictionary definition that talks about components being rendered by extraction, those components of which would be

extracts. We've got a failed FDA definition that by its own caveat says it's not to be used and that you should use something else if you can reasonably rely on it. Or we have this Government definition in Footnote 1 that is really just flat smooth wrong, even in the context of the other two definitions.

And it's really by the endgame, the barometer of the endgame that we should judge whether or not this is, in fact, a concise, definite statement of the essential facts as provided by Rule 7. Your Honor, I think it fails to meet the standards of Rule 7 as a plain, concise, definite statement of facts, because extract, undefined throughout the course of this proceeding, even in the papers, renders Count 5 a failure to state an offense.

Thank you, Your Honor.

THE COURT: Anybody else who wanted to jump in? Go ahead.

MR. RUNKLE: Okay. Your Honor, I think this is a -- this is a factual dispute. I think that Judge Lindsay is going to decide the standard for the jury to use. And I think that the --

THE COURT: What's he going to -- where is he going to glean that from?

MR. RUNKLE: Well, I think -- we don't -- we --

THE COURT: I mean, because I'm not finding like cases

where it's been defined by a court before.

MR. RUNKLE: Uh-huh.

THE COURT: Or a statute where it's defined. Where is he going to get that?

MR. RUNKLE: So, what we charged in the indictment is that the label was false or misleading in any particular. The definition of extract is not charged in the indictment.

THE COURT: Well, how --

MR. RUNKLE: Where he's going to find it is --

THE COURT: How do you get to that it was misleading if you're not making that determination?

MR. RUNKLE: So, the Judge needs to make that determination based on the dictionary definition. I think we've said that in our brief, that --

THE COURT: What dictionary?

MR. RUNKLE: The dictionary definition that Mr. Webster just said, I think we would be happy with. We have -- when we get to jury instructions, we will -- we'll talk about it. But that's, I believe, the definition that we talked about in our briefs. That the common, ordinary usage --

THE COURT: So is that going to be become, then, the standard that's going to make this situation be uniform with like charges around the country? I'm just curious.

MR. RUNKLE: Yes. It's very important to understand that I think we're in a weird position here where they're

arguing that there should be some sort of regulation I guess with *Chevron* deference or something, but I don't believe that it's appropriate to grant any kind of *Chevron* deference in a criminal case to a definition that, as Mr. Webster said, was a non-final guidance by FDA. So we're not going to be relying on that. We're going to be relying on the common, ordinary usage of the word extract.

I would also point out that there's going to be many volumes of evidence presented on the Defendants' understanding of the processes used to create this product.

There's one other very important point I would make as to Counts 5 and 8, which I believe are the felony counts. The advertisement about ethanol extracts is, on its face, misleading for a different reason, and we talked about this in our brief, which is that they now say that it's a water extract. Well, the promotional materials state that the ethanol extract and the study that they use in order to put this ingredient in a product in the first place, the study says that you need to use a -- it's complicated, but the compound that they were trying to extract from this root was called wilfoside K1N. And when you read the paper that Mr. Willson identified this compound as a potential weight loss compound, it's very clear that that compound that could actually have any effect at all was present in this root at a concentration of something like .044 percent.

So in order for the product to actually have any type of hope of even accomplishing anything like that study, which itself had issues, they would need to be extracting something that is present in less -- you know, in 0.04 percent, so some extraordinarily small volume in there.

And so that's why the mail fraud and the intent to defraud and mislead counts stand even if there is some sort of problem with the word extract, because there's an additional level of fraud being committed here in that the active ingredient that they're seeking to put in the product, they never achieved putting that in the product but they sold it as having that -- those properties anyway. So there's an entirely different level of fraud, even assuming that Mr. Fragale is correct that what they're talking about here is a water extract. They sold it -- but they sold it as having an ethanol extract.

And in addition to that, we have draft labels where they actually started out as trying to label it as wilfoside K1N. That's what they were looking for. When they didn't find it, they essentially just put something else in, which may or may not have even been related to any of these weight loss properties that they were selling.

In addition to that, I would point Your Honor to the basis for this -- a lot of the basis for this -- these counts in the indictment, which is that Mr. Geissler told Cy Willson that what they were using was not an extract and that maybe they

should take it out down the road, which shows that they have a -- they know -- they have an understanding of what extracts are. And I think it is the common understanding of what extracts are, which I think is very similar to the dictionary definition that Mr. Webster just talked about, which is that you take some sort of component out of a product, and you have a target of taking a component out of a larger biomass. And I think that that's, you know, it's an important point.

And then what happened was apparently Mr. Doyle got wind of the fact that they were mislabeling their product because he saw this email that said, hey, we're not using an extract. And then, you know, to cover that up, Mr. Geissler apparently lied to Mr. Doyle and said, no, it is an extract, it's just a water extract. Of course, the actual evidence shows that it was a pulverized root product, and a pulverized root product, I don't even know whether that would qualify as a water extract. So these are all factual disputes that are going to be in front of the jury.

Thank you, Your Honor.

THE COURT: Reply?

MR. FRAGALE: Yeah, very quickly. I would just note that the Government's theory now is that Mr. Doyle made a valid -- posed a valid question and was lied to, and yet Mr. Doyle remains charged in the indictment. So I think that's a new theory.

Second, I think factually the Government just made our argument. There was a draft label that referred to the end product using an ethanol extract. And when they determined that they weren't using an ethanol extract, they changed it. As with respect to the advertisement. It says that they have cynanchum auriculatum root extract, and they describe what that is. Then they refer to studies. Those studies refer to ethanol extract. If they wanted to mislead the consumer, instead of saying, "More recently, ethanol extracts derived from the roots" blah blah blah, they could have said, "More recently, extracts from the roots of this herb have been studied." They didn't do that because that's not what the study said.

And finally, with respect to the idea that we're now trying to pick the standard upon which to judge these statements, you would think prior to indictment the Government would have come to that decision, would have included it in the proposed indictment and presented it to the grand jury. Obviously, they did not, which is why it's not in the indictment.

THE COURT: Mr. Webster, did you want to add any more?

MR. WEBSTER: No, thank you, Your Honor.

THE COURT: Does --

MR. RUNKLE: Can I just point out one thing, Your Honor? I apologize.

THE COURT: Okay. But you don't get the last word.

Go ahead.

MR. RUNKLE: I know I don't get the last word. The one thing I just wanted to point out for the record is that Mr. Doyle is not charged with any of the fraud-related counts, any of the fraud-related counts relating to the cynanchum auriculatum extract. That's why, I mean, he is not charged in Count 8, which is the felony. And so it's not a new theory. It's that Mr. Willson and Mr. Geissler and USPLabs knew about the misbranding with the intent to defraud or mislead. And the bottom line here is that they were trying to sell a weight loss product that didn't have the active ingredient that they were trying to tout. That's the bottom line for these counts.

Thank you, Your Honor.

THE COURT: Okay. So, to move on to 387 and the motion to dismiss as to Count 6, obstruction of an agency proceeding.

MR. WEINGARTEN: I think this is it for me, Your Honor. So, when you are doing this as long as I've been doing it, both as a prosecutor and defense attorney, I think one thing you know -- and almost all my work is in the federal system -- you know Chapter 73, the obstruction of justice statutes. And so, generally speaking, the common understanding I believe for most people who ply these waters is 1503 is the omnibus obstruction statute that relates to stuff that happens in courts. 1505, stuff that happens, agencies. 1512, you mess

around with witnesses or informants or victims. And 1510 and 1519 are when you mess around with investigations.

I think the general -- certainly, my understanding is, you know, there is a line, a demarcation between sort of the investigative process, which is important, and the formal proceedings that are in court or before an agency where there's process. And I certainly have always believed that 1503 and 1505 fit in the second category, and certainly 1512 too when it came to formal proceedings.

It is true, they charge 1505. There are some old cases that suggest that sort of the police activity itself can be the subject of 1505. I actually was quite surprised to see them, but they exist. I think the better law is in our brief. I think the -- probably the most compelling is the ***Senffner*** case that sort of says precisely what I'm talking about. A mere police investigation versus the authority to issue subpoenas, and one is 1505 and one is not.

I mean, I find the language in ***Ramos*** compelling, and obviously I know that that's a 1512 case and not a 1505 case. But a proceeding and official proceeding have to be, in my view, first cousins. So, I mean, I think we have the better law. I think they're -- obviously, an FDA inspection is important, but an FDA inspection is not a proceeding, a formal proceeding as that is understood in the law.

Now, what is true is when we first drafted our brief, and

certainly my impression was what the Government was charging in Count 6 was the FDA inspection that took place at USPLabs and elsewhere when they physically showed up and went through the inventory and made judgments, and they were there about a month. And when I looked at the dates of the count, they corresponded with that more or less.

And what is true, when you technically -- not technically -- when you carefully look at the indictment, Count 6, and when I read their response, they are talking about the overall investigation, not simply the inspection. I'm not certain exactly what the agents were doing in addition to that. I assume they were doing something. So, in that sense, we stand corrected.

But what is also true is that I think it's useful to take a careful look at the conduct that they charge as being the obstructive conduct, you know, right out of the indictment. And, you know, the context is, obviously, the primary thrust of the investigation in October 2013, the FDA showing up at USPLabs and going through the stuff. What do you have? How do you keep records? What is this? And, you know, that's got to be the centerpiece of their obstructive theory.

So what do they charge we did by way of obstructing that effort? Promising FDA that it would cease distribution of the product. I -- my understanding, and if I'm wrong I'm sure I'll be corrected, is what was represented to them by Covington &

Burling was that they would cease domestic distribution, never hiding the fact that if somebody in Brazil wanted to eat this stuff three times a day, there was no law preventing that from happening and they could sell it there.

Number two, selling as much OxyElite Pro as it could as quickly as possible thereafter and attempting to ship the rest of the stuff in its possession out of the United States. Again, I mean, I'm not an FDA expert. I believe at the time the product was sold, there was not a prohibition, a legal prohibition. They weren't selling something -- it's -- an analogous situation would be a DEA agent coming to someone's house. An obstruction would be if, while knocking on the door or breaking down the door, somebody was flushing the drugs down the toilet. That would -- I don't think that's what happened here. I think they were legally and effectively selling product without any legal prohibition whatsoever.

Then they talk about conducting such sales over the phone, quote, in order to avoid creating a paper trail. Last time I use the phone, I mean, law enforcement agents have every ability to track those phone calls through phone records and every other way. So, I mean, that cannot be a serious assertion.

And then, finally, failing to provide material information about OxyElite Pro, Elite Pro, the anticipated shipments thereof, and promotional activities therefor. I mean, so what

they're saying is part of the obstructive activity is no one with no duty to do so provided them with information that they wanted. Under the law, if there's no duty to speak, and this has been the law as long as I can remember, there's no obligation to do so and there's no criminal penalties associated with the silence.

So the long and short of this, I mean, I think they picked the wrong statute. There are statutes that protect investigations. 1519 comes to mind. Certainly, 1510 if the facts fit. But on top of that, the actual conduct alleged does not fit obstruction. And I think actually this is the easiest call of all. Whatever else this conduct is they may or may not like, they picked the wrong statute. The conduct they're identifying is not obstructive conduct.

THE COURT: Yes, sir.

MR. RUNKLE: Your Honor, just a few points on this. I think that the case law on 1505, as Mr. Weingarten said, 1505 is a different statute than 1512, which is the ***Ramos*** decision. I feel like the judges who decided ***Ramos*** would be very surprised that in deciding that an informal internal personnel investigation at Customs and Border Patrol, in deciding that that was not an official proceeding, they had somehow allowed people to, you know, tell lies and make misrepresentations to FDA during statutorily-authorized inspections.

In terms of the facts that Mr. Weingarten was just arguing,

I have a lot of responses to those, but I don't think that that's entirely necessary. I'll just point out that what constitutes obstruction in this case is a fraud pattern of conduct. This was not USPLabs' first rodeo with FDA. It had been going on for a long time with FDA. By this point, there was a -- there were statements made both to FDA and to the public about how they were cooperating in this investigation, they thought their product was safe. They told FDA with no qualifications that they would cease distribution of this product. That was an email from Mr. Miles to the district director of the FDA regional office. There was no qualification made about domestic distribution. FDA is very concerned about companies shipping products that cause liver failure overseas, and has authority to take action in that instance.

And sort of interestingly, what Mr. Weingarten described as the classic obstruction is somebody's knocking, the police are knocking on the door and you're flushing the drugs down the toilet, there actually is very analogous evidence in this case that they knew FDA was coming and they were trying to get the stuff out of their warehouse as fast as they could.

There is a lot of evidence in this case that fits a pattern of obstruction of an agency proceeding. And under their argument, even accepting their argument that an agency proceeding has to have certain formalities to it, there was --

as I said, this was not USPLabs' first rodeo. There were many people who are monitoring, you know, the situation with USPLabs and their products and trying to make sure that these products were complying with the law, and they were lied to.

THE COURT: Any rebuttal, sir?

MR. WEINGARTEN: Yes, just this. You know, I mean, there are factual assertions that have just been made that I'm dying to rebut. I would simply say at the time USPLabs was represented by Covington & Burling, one of the most highly respected law firms in the country. Much of what they do is this kind of stuff. And they were represented by the former general counsel of the FDA. So, I mean, that's the nature of the interaction that's going on right now between USPLabs and the FDA. That's number one.

Number two, there are statu... I mean, this case -- I mean, there are just a number of examples where they used the wrong statute. I mean, the example of the -- sort of being lied -- agents being lied to, I mean, that's why God made 18 U.S.C. 1001. I mean, they just used the wrong statute here and they shouldn't get away with it.

THE COURT: Any other defense counsel want to chime in? Okay. By my count, we've covered everything. Have I missed something?

MR. SHEARIN: And Judge, I'm sorry, I should have spoken up --

THE COURT: Yes.

MR. SHEARIN: But I've got a companion to 220 and 221, and I believe it's Docket 392, motion to dismiss Counts 9 and 10 on behalf of Kenneth Miles.

THE COURT: Okay. I knew you had that. I thought we were hearing it all at the time, --

MR. SHEARIN: And that's my bad.

THE COURT: -- but go ahead. Go ahead if you want to add some argument.

MR. SHEARIN: Judge, I do -- good morning.

THE COURT: Good morning.

MR. SHEARIN: I do agree with --

THE COURT: State your name, please.

MR. SHEARIN: I'm sorry. I'm Joe Shearin, and I'm counsel for Kenneth Miles. And I do agree with the constitutionality of the basis of Counts 9 and 10, but especially --

THE COURT: You agree with the arguments?

MR. SHEARIN: Yes, ma'am. In the motions 220 and 221.

THE COURT: Okay.

MR. SHEARIN: But especially as they're applied specifically to Kenneth Miles. The Government in their response to my motion said it was unremarkable that all of the other Defendants had been charged with conspiracy or fraud or willful or intentional conduct and that Kenneth Miles is

involved in two misdemeanor -- strict liability misdemeanors. And with all due respect, I would disagree. I think it's quite remarkable that in a 37-page indictment, that Kenneth Miles is not mentioned, with all the paragraphs and pages, until Page 26 in Count 9. Again, on Count 9, and Page 27, Count 10, in two misdemeanor -- strict liability misdemeanors.

The -- and I apologize, Judge. Give me one second. The Government, in the earlier -- their earlier comments, had stated that there was a difference between the -- in these counts in the *Park* doctrine, that certain Defendants actually did in fact have personal knowledge. That is -- does not apply to Kenneth Miles. Again, he would be under strict liability. In the Government's response to my motion, it said that these people, but they also include Kenneth Miles, that they personally participated in the acts constituting the misdemeanor violations, such as the formulation, shipment, manufacture, and labeling of the adulterated and misbranded products. There -- that is not -- that does not apply to Kenneth Miles.

Judge, the -- they argue that -- and I agree with Mr. Webster. On Rule 7, the allegations against Kenneth Miles under the *Park* doctrine were insufficient. They're vague as applied to him, especially so. Because he is being charged with strict liability, not with any type of knowledge or with anything. They've used the exact same things or the charges,

the actions that involve intent and willful action in the Counts 9 and 10. And so they're, again, they're saying that the others have knowledge but Kenneth Miles would be strictly liable.

And in their response on Page 3, they say that they have sufficiently followed Rule 7 in the indictment, that they have alleged that Kenneth Miles was, quote, in charge of ensuring the compliance of USPLabs' products with the FDCA. I'm not sure what that means. The FDCA is a labyrinth. It's -- it is -- it's a very -- obviously, a very large Act. It has numerous components to it that talk about compliance in all kinds of different areas, whether it's submitting drugs to the FDA for approval, whether it's shipping products, whether it's good manufacturing practices, whether it's a number of different things. And it also addresses a number of different people. So to say that he was in charge of ensuring the compliance of USPLabs' products, to what degree? Because -- excuse me.

THE COURT: So you don't think the charge puts him on notice that the allegation is that he was responsible for making sure those portions that related to the ingredients of the products complied?

MR. SHEARIN: That's correct. Because under the *Park* doctrine, it's not just following -- and obviously, the Rules as well. It's not just following the statute. Everybody has talked about that. But sufficient facts. And there are no --

there is no definition of a responsible corporate officer in the law. We have to go by case law. But to meet the element for knowledge, to meet the element for responsibility, it's not just responsibility, it's being responsible and having the authority, having the power to prevent and/or correct the alleged violation. And --

THE COURT: Well, I know there is -- I know there is a dispute as to what his position actually was with the company, but isn't that a factual matter that the jury needs to determine?

MR. SHEARIN: No, ma'am. It is, in fact, a matter of law, and I'm going to -- and I apologize. I don't talk as fast as --

THE COURT: Well, --

MR. SHEARIN: I'm from Texas, so --

THE COURT: -- I'm with you.

MR. SHEARIN: And I appreciate it. Bear with me. In their -- the Government cites --

THE COURT: He just called y'all fast-talking.

(Laughter.)

A VOICE: We have a flight.

MR. SHEARIN: I know. You might miss it. But give me a minute. Or two.

In their brief, the Government talks about the violations, alleged violations committed by all those who have a

responsible share. What they're asking, though, in the charge is they want to have -- make Kenneth Miles, someone without knowledge, someone that lacked the authority to act or prevent or cure any alleged violation, they want to make him have a responsible share in what they've alleged to be a conspiracy and fraud.

THE COURT: But if --

MR. SHEARIN: They --

THE COURT: -- you prove that he didn't have the authority, then you win.

MR. SHEARIN: And that's where I'm going, Judge. They also cite United States v. N.Y. Fish, and they talk about liability under the FDCA attaches to all persons whose failure to exercise the authority and supervisory responsibility given to them by the business organization. Not the responsibility and the authority that the Government wants to put on him, but given to them by the business organization.

The -- USPLabs has said he was a non-control employee. There's no question he was an employee. He was a salaried employee. And by the Government's own indictment, in Count 9 when they re-allege and incorporate all the previous paragraphs, 1 through 35 and 39 through 44, when you start out, the Defendants, and you go 1, 2, 3, all the way through 7, guess who's missing? Kenneth Miles. There's no description of Kenneth Miles. But there are descriptions of the other co-

defendants. Co-founder. Co-owner. CEO. Co-founder. Co-owner. President. Co-owner. Former co-owner. With responsibilities for formulating products. Marketing. And product packaging, design, labeling. And those were -- those are what the charges are in the Counts 9 and 10.

What they have done, what the Government has done has turned the *Park* doctrine upside down. It is -- all the -- the cases that I'm familiar with, it's from the bottom up. It's who was in a supervisory role with the power and authority to prevent or correct a violation, an alleged violation? What they have done is they have made Kenneth Miles responsible, strictly liable, for the conduct that they've allege to be a conspiracy and fraud, for the conduct of his superiors. There is -- and they even admit it. They say -- they don't allege anything sufficient to show that USPLabs had given Kenneth Miles the responsibility and the authority and power to prevent what they've alleged. They are trying to hold him strictly liable for the actions of his superiors who in fact -- you know, Kenneth Miles, it's not the buck -- the buck doesn't stop with him. It doesn't even start with him. And he is in a very unique position in these charges, and he is not, in fact, a responsible corporate officer.

And with that, I would ask that you dismiss Counts 9 and 10 as to Kenneth Miles for those reasons. Thank you, Judge.

THE COURT: Thank you, sir. Response?

MR. RUNKLE: I'll just rely on my argument earlier. Thank you.

THE COURT: Okay.

MR. HALL: Your Honor?

THE COURT: Yes, sir.

MR. HALL: Patrick Hall.

THE COURT: Would you come up to the mic? I hate to make you move, but the recording can't get you unless you're in the microphone.

MR. HALL: Your Honor, I believe you had calendered Motion No. 376 for argument today as well, and that is a discovery-related motion that's unique to Mr. Patel and SK.

THE COURT: Okay. And I have to admit that, unfortunately, it wasn't on my long list, and so I'm not as familiar with it as I should be, but I'm ready to hear your arguments.

MR. HALL: Thank you, Your Honor.

THE COURT: Because I know it was mentioned in that order.

MR. HALL: Your Honor, in essence, what SK and Mr. Patel are seeking are three things in discovery. One is what we'd categorize as the documents that the search team, after they searched through the computer hard drives, turned over to the prosecution team. The second item is the experts' reports that conducted the searches of those computers.

THE COURT: Haven't we heard this before? Was that this case? We have heard these -- these arguments before and already ruled on that?

MR. HALL: You have not, that I --

THE COURT: I've not?

MR. HALL: Unless I was asleep, Your Honor, I don't think you --

THE COURT: Okay.

MR. HALL: -- you have. Because this is -- this is somewhat unique because this is the California warrant which imposed a certain protocol for the manner in which SK was to be searched, compelling that the search team use a certain protocol when they searched the hard drives and the computers.

THE COURT: Okay.

MR. HALL: And I think that certain issues have been raised before by USP regarding searches and attorney-client privilege, but this is a unique --

THE COURT: Okay.

MR. HALL: -- unique request. And so then the last thing that we are requesting are the Court ordered that notes be prepared when the search was being conducted of the hard drive, and we're seeking those.

But I'd like to focus my comments primarily on that first category, because it may, frankly, moot the second two categories. And the factual background is important. When

they executed the search warrant in November of 2013, the agents came in and they searched a number of hard drives and mirror-imaged all of those hard drives. There were multiple hard drives, including a hard drive that belonged to a CPA that was renting one of the offices there that was also searched and mirror-imaged and then put onto a huge database of documents.

The Government has identified that database as consisting of 1.1 million documents, and I have no reason to doubt that, the accuracy of that number.

What occurred after that is that, pursuant to the California warrant, a search team or a filter team was utilized for purposes of going through to see which documents on the computer systems were responsive to the search warrant or were the particular documents to be seized. They then filtered out approximately 851,000 documents of the 1.1 million documents, and then that left approximately 261,000 documents that were then turned over by the search team to the prosecution team.

Before they did that, of the remaining documents that were there, they also did a filter process for attorney-client privilege. And that's not what we're talking about. The Government has provided to us what I would characterize as a handful of documents, which is about -- there's several hundred attorney-client privileged documents, and they've identified from that massive 1.1 million database what the attorney-client privileged documents were.

What they have declined to do is identify what documents were turned over to the prosecution team by the search team. And so there is, of this 1.1 million minus the handful of attorney-client privilege, what the Government has given us is this entire database of 1.1 million documents. And what we're seeking by this motion is a copy of the digital data that was turned over by the search team to the prosecution team and which they are utilizing for purposes of this prosecution.

At one point, we requested the 850,000 documents that were excluded, and it appeared that the Government was going to give us that.

THE COURT: Okay. So you have everything. You just want them to tell you how they divided it?

MR. HALL: Well, I don't -- I have everything, yes. What I want is what the search team produced pursuant to the warrant --

THE COURT: You want --

MR. HALL: -- and gave to the prosecution.

THE COURT: You want them to tell you what they thought was relevant --

MR. HALL: No.

THE COURT: -- to the charges?

MR. HALL: Well, no, because it's two different teams. And so I think it's important to distinguish between the search team and the prosecution team. This is the prosecution team

seated here today.

THE COURT: Right.

MR. HALL: And they didn't get to do that filter process. It was done by a separate --

THE COURT: Right.

MR. HALL: -- a separate part. And they then seized from that what was responsive according to their search, according to the warrant.

THE COURT: Right.

MR. HALL: And it's that that I am seeking. It's what was seized within the meaning of Rule 16. And I think it's kind of a unique argument, given the nature of the search here.

THE COURT: I think we've actually heard that here before as to USPLabs, but go ahead.

MR. HALL: Well, I think this is a different one because the warrant that was utilized compelled that the search team conduct this special type of search, given the nature -- the electronic media nature. And what we're talking about is that if they had gone in and seized all the physical documents, all right, and then returned some of the physical documents because they weren't responsive, we would know exactly what it is that they still kept because they'd have to give us a copy of that. But here, they've gone in and they've seized everything and they are declining and refusing to give us what it is that's actually turned over to the prosecution team as

responsive to the search warrant.

And so I think that this is a direct interpretation of Rule 16 of what items were seized, and I think the term seized we have to interpret in a more modern context than it was originally contemplated when the Fourth Amendment was developed or when Rule 16 was first written. Because we're talking about electronic media, and so when you go in and you mirror-image everything, you get everything. But what they actually seized and turned over for the prosecution team to inspect is what we're seeking.

And I think it's an easy product for the prosecution team to give us that because it's what they got from the search team. And so it's not -- I'm not looking for any thought processes or mental impressions of what's relevant and what's the most relevant documents. And I think in their response the prosecution called it -- what we're seeking is the prosecution attorneys' views on what constitute the most relevant documents. No. What we're looking for is what was seized and turned over to them pursuant to the warrant. And that constitutes a realm of approximately 261,000 documents, so we're not talking about --

THE COURT: Let me ask you this.

MR. HALL: -- the key exhibits.

THE COURT: Even if your argument, you know, I find that that's -- your argument has merit, in an analogous

situation, say they seized and turned over everything to them, do you think they were supposed to list out individually and describe each of the documents that were turned over to them in order to comply with Rule 16?

MR. HALL: No. No, I don't, Your Honor, because it was all turned over to them. What's missing here is we don't know what's turned over to them.

And here's what the dilemma is. The dilemma comes up in two contexts. One is they get --

THE COURT: But if everything was turned over to them, and you know everything was turned over to them, --

MR. HALL: Then we would know what they were looking at. And here's what my dilemma is. It's, yesterday there was some discussion about we haven't turned over a page of reciprocal discovery. And so we're looking at this database of 1.1 million, of which they apparently can only see 261,000 documents. The search team determined that these other 850,000 or whatever the number is -- I'm bad at the math -- was not responsive to the search warrant. When we're going through that database, we may find documents that, one, they may have missed. Or two, may be something that we want to introduce in the case in chief. We have no idea whether we have to produce that to them as reciprocal discovery because they haven't seen it and we have no way to make that determination. And that's one of the dilemmas.

The second dilemma is this. When we raised an issue, they gave us some search terms and said, you can figure it out yourself. They gave us the search terms, and then we used those search terms, and when we applied those search terms, we found that one of these text messages that had been referred to that was seized from Mr. Patel's cell phone, also part of this, one of those text messages came up in the bail hearing. And when we applied those search terms that they gave us, it didn't show up in the search. And so we said, well, how can this be? And we filed a supplemental motion. In response to that motion -- and that's not a motion that I think has been referred to Your Honor. I think that's Motion No. 410 that's before Judge Lindsay. And I'm not asking you to address it.

THE COURT: Is it related to that one?

MR. HALL: Well, it is, because here's what the -- here's what we've learned.

THE COURT: That relates to it?

MR. HALL: It does relate to it. It's a supplemental suppression motion. And I think he has kept all of the suppression motions for himself.

But what occurred when we raised this motion is they told us that there was yet a different type of search, that there was a random sampling and a quality assurance phase where the filter team manually reviewed a statistical sample of documents that had not hit on the relevant search terms.

So, in addition to the search terms, there was some other search that was conducted, and we don't know what that is. And apparently this text message was turned over by the Government in response to that. And their document is 410, is their response that contains this explanation.

And so where we are is we don't know exactly what they're looking at. They have 1.1 million. It's within that realm. But what we're simply asking for is, when that search team narrowed down what was relevant, not the prosecution team's determination as to what was relevant when they said, and it's not relevant. What was responsive to the warrant, what were the particular documents that could be seized, when they turned those over to them, they're declining and refusing to produce that. And that's what this motion is directed to. That's what we're looking for.

Frankly, Your Honor, the notes and the computers' experts, we're also seeking, but I think those are mooted if Your Honor would order them to give us that universe of documents that was turned over after the search.

Thank you.

MR. RUNKLE: So, I'll take the last point first, this point about this text message and the manual sampling review. Obviously, I didn't conduct any of those things. In -- we filed *ex parte* with Judge Lindsay an explanation and documents supporting how that text message got into our hands. And so

that's filed *ex parte* on the docket. I assume Your Honor could take a look at it.

So, this motion suffers some of the same flaws as the motion from last summer that was about the filter team as it related to USPLabs. But there's an additional flaw with this motion in that there's no constitutional or statutory basis for the relevance review that was conducted in California at all. This is why the courts in the Central District of California are no longer using these protocols, the *CDT* protocols. And the Ninth Circuit has held that the *CDT* protocols are unnecessary in several published opinions since 2010, and especially in searches of business organizations. There's a Ninth Circuit case I believe called *Schesso* or *Schesso* that explicitly holds that the *CDT* protocols that were used in this case are unnecessary.

And so our position is that there's no basis to order any of this discovery because it would have been legal for us to look at all of it anyway.

Now, we did comply with the terms of the warrant and we'd be willing to prove *ex parte* to the Court that we did comply with the terms of the warrant and the way that the search was conducted. But I believe --

THE COURT: Let me ask you. What would it entail, what would it do, just get past principle, what would it mean to just share with them what you actually took?

MR. RUNKLE: Okay. So there's -- there are two issues with that. One is that we were going to give them the material that was filtered out as non-relevant or nonresponsive. They took the position in their motion that the warrant forbids us from giving that to them. The warrant says that it's not to be accessed by the Government after the relevance review is conducted.

So we have no -- and we looked at the warrant, and it indeed does say that. That stuff is not supposed to be touched by the Government, and that's why the ***CDT*** protocols are so unworkable. So I have no confidence that the database that I have or the materials that I am looking at, I don't know what additional processing was done, what documents were taken out of there, what documents -- you know, there could be mislabeling in my own database. What I know is that the search team filtered out 800,000 documents that I'm not allowed to look at or provide to the Defense, especially given their argument that it would violate the warrant to give them those documents.

We are perfectly happy to give them the non-relevant documents, and we made attempts to do so, but then they started arguing that that would violate the warrant. So I don't know if somebody has to go to, I mean, the magistrate judge --

THE COURT: So there wasn't like a -- there wasn't a server -- I guess you, with that number of documents, you

wouldn't need a server -- but there wasn't like a medium with which you were presented that represented the portion that was not the 800,000-and-something documents?

MR. RUNKLE: Right. So, what -- so, my understanding is that -- the answer is no. That was done electronically. But it was not, from what I recall, delivered in exactly -- in one batch. It was not delivered in one batch. So it becomes a much more complicated procedure.

In addition to that, my understanding from years ago was that one of the USPLabs, and this is an additional problem with what Your Honor is asking, is that one of the USPLabs search warrant drives originally was mislabeled as an SK Labs search warrant drive and went through the relevance filter process by accident. And I didn't do any of this so I have no idea about the specifics of this. And so, in unwinding that issue, which actually would have led to better protection for the Defense because the USPLabs document, but I believe that that issue was unwound.

But what I'm saying is that I don't believe by just exporting out the 200,000-some documents at SK Labs, and I don't even know if that's the number, I've never -- I've never calculated it -- exporting them out of my review database is actually going to give Mr. Hall what he wants. And so there would have to be -- the better way to give Mr. Hall what he wants is to give him what I know the search team can access if

they would be authorized to, which is the 800,000 documents that were filtered out.

THE COURT: And what does authorization, I mean, what does that mean?

MR. RUNKLE: I --

THE COURT: Does that mean going back to the California court, asking?

MR. RUNKLE: I don't -- I don't know. I guess that's what that would mean, that we would need to -- maybe we could do an unopposed motion. I mean, as I said, the biggest problem that I have with this is that there's no -- especially given the case law now in the Ninth Circuit, there's no statutory or constitutional basis for this whatsoever.

I believe what Mr. Hall really wants to do is file additional discovery motions about, you know, that we have seen non-relevant stuff. But the problem is that then we're just going to have more motions about the, you know, about the ***CDT*** protocols and whether they are properly implemented and where they should apply. And so I don't believe where we're going here is a good direction.

But as I said, we offered to give them the non-relevant documents that would have let that happen, but no, they -- instead of accepting our offer or going to the California court, they filed a motion saying that we weren't allowed to do that. And now we're six months later. And, you know, the

Government is ready to go to trial in September, and I don't believe that this is going to help anyone get to trial in September.

THE COURT: Okay. Well, --

MR. HALL: May I respond, Your Honor?

THE COURT: Yes.

MR. HALL: First, when we requested access to the attorney-client privilege documents that were filtered out, there was a request made to the search team and the search team produced those documents to us. And so when Mr. Runkle is proposing that that somehow violated the court order, they've already done that and given us the attorney-client privileged documents. And so it's the same process that could be utilized to identify the 851,000 documents that they excluded that would identify --

THE COURT: Well, why did you object, then, to them giving you the 851,000?

MR. HALL: We did not. We requested it, and they did a change in position in February, after this motion had been filed. They said they were in the process of giving that. There's no motion filed objecting to that process.

And so when he represents to the Court that we've objected to it, that's not accurate. That's not part of any of the motions. And we would welcome that. We specifically asked it, and I think that we included in the discovery motion some

access to some of the emails and the correspondence requesting the items. So that's a flawed analysis.

He also argues that the warrant is no longer compelled in this manner in California. But --

THE COURT: The execution of it?

MR. HALL: The execution. So these protocols are no longer the law in California. But the point that's made is that these documents were seized pursuant to that warrant. All right? And they want to just ignore the fact that the documents were seized pursuant to that warrant, and I think that we're entitled to know what documents were seized pursuant to the warrant.

THE COURT: Okay. So, if they gave you or provided you with the 851,000 or so documents that were not seized technically, then you would be satisfied?

MR. HALL: Yes.

THE COURT: Okay. And your, Mr. Runkle, again, your basis for not doing that is because you were going to do that and somebody brought to your attention that it violated something?

MR. RUNKLE: No, Your Honor, I'm reading Page -- I'm going to read to you from their motion. It is Page 13 of Docket 376. It says, "The fact the Government still has that deleted or excluded data appears to violate the express terms of the search warrant. At the very least, the Government was

ordered not to access that data absent a court order."

It can't be any clearer.

THE COURT: How about --

MR. RUNKLE: What Mr. Hall just told you is not correct.

THE COURT: -- if you now have a court order that permits you to turn over those 851,000-plus documents that you did not technically seize?

MR. RUNKLE: We will do so, Your Honor.

MR. MCMULLEN: Your Honor, I'm sorry. Can I be heard --

THE COURT: Yes.

MR. MCMULLEN: -- for a moment just in response to that? Joseph McMullen for SK Labs. I'm also on this motion. And frankly, some of the review of these documents are going to fall on me, and so I want to address why I think -- why I think there's a problem with that 850,000 being turned over. And that is, one, there are duplicate -- there are certainly duplicate documents, and so turning over to us 850,000 documents that they're saying they have not seen still does not tell us what is in play here.

THE COURT: Well, but you have the whole. You have the whole, you minus what they don't have, and you know what they have.

MR. MCMULLEN: Your Honor?

THE COURT: That's just simply math.

MR. MCMULLEN: Here's why that's not necessarily true. If we receive from them a document, it is something that was not -- that was filtered out. There's duplicates, and so we don't know, if we compare that filtered-out document with the whole, if there is a duplicate of that document that they do have. That's why we can't do the math.

THE COURT: I don't get that. I'm really having trouble understanding that. If they took a finite number of documents out of the whole and kept the remainder, regardless of whether it contained some duplicates or whatever, you know they have it because it's not in what you have.

MR. MCMULLEN: Here is the problem with that as well.

THE COURT: Because you have duplicates, too, in the whole.

MR. MCMULLEN: Right. Your Honor, I --

THE COURT: Yeah?

MR. MCMULLEN: Yes. I suppose that would be the case if there would be consensus on what the total number of documents is. They've estimated it at 1.1 million, but --

THE COURT: I thought you had those back.

MR. MCMULLEN: We have everything.

THE COURT: Okay.

MR. MCMULLEN: But the idea that there is agreement about how many documents that constitutes, when we're dealing

with files like Excel files and whatnot that do not necessarily reduce to a page, we can't tell if it's really 1.1 million documents.

The bigger picture is this, Your Honor. All we want -- we don't want their playbook. All we want to know is the boundaries of the field. And what they've given us is a whole blueprint of AT&T Stadium. And then they're saying, well, and we'll tell you there's bleachers here and there's bleachers there and we haven't seen that. We don't need to know all that stuff. We just need to know what is in play. And that's --

THE COURT: Well, they're saying we kept Sections AA and BB and here are all the rest of the sections we didn't keep. Now you know what we kept.

MR. MCMULLEN: If it were simple where it was AA and BB that would be fine, but here there's a number of --

THE COURT: I think you --

MR. MCMULLEN: -- duplicate files and documents.

THE COURT: I think you're making some assumptions based on not having it yet.

MR. MCMULLEN: No, Your Honor. Because we have the universe.

THE COURT: Okay.

MR. MCMULLEN: We have the universe of -- you know, we have the entire map of Dallas.

THE COURT: But you don't have what they didn't give

you. But when you do, then you can look at it and see --

MR. MCMULLEN: Well, but --

THE COURT: -- if there's an issue.

MR. MCMULLEN: Your Honor, the reason we won't be able to is because several of those files, you can't -- you can only estimate how many pages that constitutes. An Excel file, for example. And so if they show us, well, there is an Excel file here that's in that 850,000, we can't assume that that's not also something that's in the 260,000 that they've looked at, because they could have filtered it out through one process but not through another.

It's -- and the other thing is this, Your Honor. We've been asking for this for a long time. And we're --

THE COURT: Well, now you get it.

MR. MCMULLEN: And, well, but we're a few months out from trial. And what -- all we're asking for is still a universe of 260,000 documents and to say, this is what is in play for this trial. Giving us 850,000 and having something that we estimate at 1.1 million and then us, me, having to go and not have the Eastern-educated lawyers and the army to review all that kind of stuff is just -- it's so overwhelming to us at this point that we cannot be prepared to filter -- to figure out what is in play. And the way that's going to work out at trial is what we just talked about.

THE COURT: But what you want to know is what they

looked at, because if they're using some documents, you're going to get them. You're going to get copies of them. So you just want to know what they reviewed.

MR. MCMULLEN: That's not -- no, Your Honor, that's not the case. What we want to be able to do is to know that this is the universe of documents, the 260,000 documents from -- seized from SK Labs --

THE COURT: That they could have possibly seen?

MR. MCMULLEN: That are in play. And so during the trial we can -- we can -- if some testimony comes up in the middle of trial, we know that we can cross-examine, all those sorts of things, and that there's no additional discovery obligation at that point where they can say, well, you never gave us these documents, when they're the ones who seized them. We can't -- we just can't do that analysis at this point.

And I -- these -- I don't --

THE COURT: I'm not finding that particularly convincing.

MR. MCMULLEN: Your Honor, I guess what I don't understand --

THE COURT: Uh-huh.

MR. MCMULLEN: -- is this. The Government has talked about the difficulty of finding out all the -- of being able to access the things that are out of bounds so that we can extrapolate and deduce the 260,000 documents that are in play

for this trial. And so --

THE COURT: Come back to me if there are -- with some particular issues if that doesn't work. But right now, that's going to be the order.

MR. MCMULLEN: So the order is that we will receive, though, the 850,000 documents?

THE COURT: Right. What they were getting ready to give you before all this came up, they now have authority to do, and so I'm ordering them to do it then. And then if there is an additional issue and we don't have to speculate about it, then you can come back with some particulars.

MR. MCMULLEN: Your Honor, I -- what I would ask is this, then. That their -- that the 850,000 documents be -- and that the Government represent when they turn that over that those are documents that have not -- that are not in the 260,000.

THE COURT: Well, that's the universe. That's what the order is.

MR. MCMULLEN: Okay. So at least they, if they want to do it that way, where we have to make some deductions, --

THE COURT: That's what the order is.

MR. MCMULLEN: Right. But so the understanding is clear, that if those are filtered out --

THE COURT: If they follow the order.

MR. MCMULLEN: Right. But if they're filtered out,

that they have made sure that those filtered-out documents do not also exist --

THE COURT: They might.

MR. MCMULLEN: -- independently in the 260,000.

THE COURT: Because they might be duplicates on what they seized. They might be duplicates in what they seized. But you know which ones of them you got back so you should be able to exclude them.

MR. MCMULLEN: Understood, Your Honor. Thank you.

MR. RUNKLE: Your Honor, I just have one additional request on that. If Your Honor can make clear to Mr. McMullen that he's not to share this discovery with his other client in California who is suing the Government about the execution of the search warrant. There's some dispute about how Mr. McMullen is getting information to prosecute or litigate his case against the Government based on that CPA computer that we seized.

THE COURT: Okay.

MR. RUNKLE: I'm a little bit concerned here about that.

THE COURT: Okay. I don't understand that.

MR. MCMULLEN: Your Honor, --

THE COURT: Because if you -- if you don't seize a thing and it belongs to them, you give it back to them. So what? They do with it what they want to. I don't understand

that.

MR. RUNKLE: Which -- so, Your Honor, I'm concerned that Mr. McMullen is --

THE COURT: Is this something you haven't seized?

MR. RUNKLE: No.

THE COURT: So you're giving it back?

MR. RUNKLE: Mr. McMullen is seeking information about the Government turning over tax returns that were on the CPA computer for a lawsuit that he filed in California against the Government, --

THE COURT: Uh-huh.

MR. RUNKLE: -- and I just want Your Honor to make very clear that this information that the Government is turning over pursuant to Your Honor's order is not to be discussed in that -- or any of these discussions today are to be used to litigate that lawsuit in California. It's a very simple request that I'm making.

MR. MCMULLEN: Your Honor, there's a protective order in this case. I'm familiar with my obligations under the protective order. Judge Lindsay signed that order.

THE COURT: Okay.

MR. MCMULLEN: And I will not be violating that order.

THE COURT: So we'll make the production pursuant to the protective order.

MR. RUNKLE: Thank you, Your Honor.

MR. MCMULLEN: Thank you, Your Honor.

THE COURT: All right. We're adjourned.

MR. HALL: Thank you.

THE CLERK: All rise.

(Proceedings concluded at 11:44 a.m.)

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CERTIFICATE

I certify that the foregoing is a correct transcript from the digital sound recording of the proceedings in the above-entitled matter.

/s/ Kathy Rehling **06/06/2018**

Kathy Rehling, CETD-444 Date
Certified Electronic Court Transcriber

INDEX